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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,669	02/09/2001	Jiangchun Xu	210121.427C24	8247
500	7590	06/22/2004	EXAMINER	
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC 701 FIFTH AVE SUITE 6300 SEATTLE, WA 98104-7092			HELMS, LARRY RONALD	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 06/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/780,669	XU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Larry R. Helms	1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-20 and 22 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group II in Paper filed 4/12/04 is acknowledged. The traversal is on the ground(s) that the all groups encompass a generic claim number 18 and it would not be a serious burden to search the claimed species. This is found persuasive and all claims 18-22 will be examined.
2. Claims 18-22 are pending and under examination.

### ***Information Disclosure Statement***

3. The IDS filed 2/9/01 and 10/19/01 were placed in the file and will be considered when copies of the references are provided. Because of the lengthy priority data it is unclear which applications have the cited references. It is requested that applicant provide a copy of all references and they will be considered at that time.

### ***Specification***

4. The disclosure is objected to because of the following informalities:
  - A. The first line of the specification needs to be updated to indicate which applications are now patents and which are abandoned. In addition the continuation data should indicate that all applications are CIPs.

Appropriate correction is required.

### ***Priority***

5. The instant application is a CIP of several applications. Claim 18 recites a compositions comprising a first component either carriers or immunostimulants and a second component of an antibody or antigen binding fragment that binds SEQ ID NO:114. The first apparent mention of the limitation of "immunostimulants" is seen in the 09/439,313 application. Therefore the claims are granted the priority of the 09/439,313 application which is 11/12/99.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 18-20 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Hillman et al (US Patent 6,020,478, filed 2/28/97).

The claims recite a composition comprising a carrier and an antibody to SEQ ID NO:114 wherein the antibody is a polyclonal or monoclonal and the composition is effective for inhibiting tumor growth. For this rejection the intended use for inhibiting tumor growth is given no patentable weight for claim 22.

Hillman et al teach SEQ ID NO:1 which is identical to the instant SEQ ID NO:114. Hillman et al teach polyclonal and monoclonal antibodies to the protein and carriers and the antibodies can be used for treatment of cancer (see column 7, column 16, lines 20-65, column 19, lines 45-60, column 21, lines 30-50).

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1642

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 18-20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillman et al (US Patent 6,020,478, filed 2/28/97) and further in view of Gillies (US Patent 5,650,150, issued 7/97).

Claims 19-20 and 22 have been described supra as well as the interpretation of claim 22, claim 18 recites a composition comprising an antibody to SEQ ID NO:114 and an immunostimulant.

Hillman et al has been described supra. Hillman et al does not teach an immunostimulant with the antibody. This deficiency is made up for in the teachings of Gillies.

Gillies teach fusion protein comprising anti-tumor antibodies and cytokines for the treatment of tumors.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced a composition comprising an antibody to SEQ ID NO:114 and a cytokine for inhibiting tumor growth.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation to have produced a composition comprising an antibody to SEQ ID NO:114 and a cytokine for inhibiting tumor growth because Hillman et al teach antibodies for treatment of tumors and Gillies teach antibody cytokine fusion proteins for treatment of tumors wherein the antibody binds to a tumor antigen and the cytokine

results in stimulation of a T cell response (see column 3 of Gillies). The antibodies of Gillies are from Ig-producing lymphoid cells and as such it would be obvious that they can be either polyclonal or monoclonal (see column 6 and 7). Since claim 1 does not recite that the components are separate components a fusion protein of an antibody and a cytokine would read on the claims. Thus the are reads on the claims.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

9. Claims 18-20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillman et al (US Patent 6,020,478, filed 2/28/97) and further in view of Fujiwara et al (Cancer Chemother Pharmacol 38:s22-26, 1996).

Claims 19-20 and 22 have been described supra as well as the interpretation of claim 22, claim 18 recites a composition comprising an antibody to SEQ ID NO:114 and an immunostimulant.

Hillman et al has been described supra. Hillman et al also teach antibodies can be used to treat cancer and the antibodies can be combined with other therapy such that one may achieve therapeutic efficacy with lower dosages of each agent, thus reducing the potential side adverse effects (see column 16, lines 36-52). Hillman et al does not teach an immunostimulant with the antibody. This deficiency is made up for in the teachings of Fujiwara et al.

Fujiwara et al teach treatment of tumors with IL-12 and the addition of IL-12 leads to tumor regression (see entire document).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced a composition comprising an antibody to SEQ ID NO:114 and a cytokine for inhibiting tumor growth.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation to have produced a composition comprising an antibody to SEQ ID NO:114 and a cytokine for inhibiting tumor growth because Hillman et al teach antibodies for treatment of tumors with other agents so that lower dosages can be used. In addition, one of ordinary skill in the art would have been motivated to and had a reasonable expectation to have produced a composition comprising an antibody to SEQ ID NO:114 and a cytokine for inhibiting tumor growth because Fujiwara et al teach that the cytokine IL-12 leads to tumor regression.

The motivation to combine can arise from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combine for their common known purpose. Section MPEP 2144.07. Versus See MPEP 2144.06.

It is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. In re Kerkhoven, 205 USPQ 1069, CCPA 1980. See MPEP 2144.06.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.



**Conclusion**

10. No claim is allowed. Claim 21 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, <sup>CHRISTINA CHAN</sup> ~~Yvonne Eyer~~, can be reached at (571) 272-08<sup>411</sup>~~71~~.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Respectfully,


Larry R. Helms Ph.D.

Application/Control Number: 09/780,669

Page 9

Art Unit: 1642

571-272-0832



LARRY R. HELMS, PH.D  
PRIMARY EXAMINER